AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. Contract ID Code	Page	of Pages
	1	5

2. Amendment/Modification No.	3. Effective Date	4. Requisition/Purchase Req. No.	5. Project No. (if applicable)
A002	See Block 16C		

6. Issued By	Code 000SB	7. Administered By (If other than Item 6)	Code
NATIONAL INST OF STDS AND TECHNOLOGY 100 BUREAU DRIVE STOP 1640 BUILDING 301 ROOM B125 GAITHERSBURG, MD 20899-1640 MICOLE CHEATHAM 301-975-8335		SEE BLOCK 6	

8. Name and Address of Contractor (*No., Street, County, and Zip Code*)	(X)	9A. Amendment of Solicitation No.
		NIST-11-SBIR
	X	9B. Date (*See Item 11*) 11/04/2010
		10A. Modification of Contract/Order No.
		10B. Date (*See Item 13*)

Code	Facility Code

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

[X] The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offers [ ] is extended [X] is no t extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing items 8 and 15, and returning [1] copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. Accounting and Appropriation Data (*if required*)
$ US 0.00

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(x)	A. This change order is issued pursuant to: (*Specify authority*) The changes set forth in item 14 are made in the Contract Order No. in item 10A.
X	B. The above numbered Contract/Order is modified to reflect the administrative changes (*such as changes in paying office, appropriation date, etc.*) Set fourth item 14, pursuant to the authority of FAR 43.103 (b)
	C. This supplemental agreement is entered into pursuant to authority of:
	D. Other (*Specify type of modification and authority*)

E. IMPORTANT: Contractor [ ] is not, [X] is required to sign this document and return 1 copies to the issuing office.

14. Description of Amendment/Modification (*Organized by UCF section headings, including solicitation/contract subject matter where feasible.*)

The purpose of this Amendment is to add pertinent new clauses (Attached pages 2-5). All other terms and conditions remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect

15A. Name and Title of Signer (*Type or Print*)		16A. Name and title of Contracting Officer (*Type or Print*)	
		ALBERT PETTO CONTRACTING OFFICER PETTO@MAIL.NIST.GOV	301-975-6338
15B. Contractor/Offeror (Signature of person authorized to sign)	15C. Date Signed	16B. United States of America (Signature of Contracting Officer)	16C. Date Signed 1/20/11

1352.235-70 Protection of human subjects. (APR 2010)

(a) Research involving human subjects is not permitted under this award unless expressly authorized in writing by the Contracting Officer. Such authorization will specify the details of the approved research involving human subjects and will be incorporated by reference into this contract.

(b) The Federal Policy for the Protection of Human Subjects (the "Common Rule"), adopted by the Department of Commerce at 15 CFR Part 27, requires contractors to maintain appropriate policies and procedures for the protection of human subjects in research. The Common Rule defines a "human subject" as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The term "research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The Common Rule also sets forth categories of research that may be considered exempt from 15 CFR Part 27. These categories may be found at 15 CFR 27.101(b).

(c) In the event the human subjects research involves pregnant women, prisoners, or children, the contractor is also required to follow the guidelines set forth at 45 CFR Part 46 Subpart B, C and D, as appropriate, for the protection of members of a protected class.

(d) Should research involving human subjects be included in the proposal, prior to issuance of an award, the contractor shall submit the following documentation to the Contracting Officer:

(1) Documentation to verify that contractor has established a relationship with an appropriate Institutional Review Board ("cognizant IRB"). An appropriate IRB is one that is located within the United States and within the community in which the human subjects research will be conducted;

(2) Documentation to verify that the cognizant IRB possesses a valid registration with the United States Department of Health and Human Services' Office for Human Research Protections ("OHRP");

(3) Documentation to verify that contractor has a valid Federal-wide Assurance (FWA) issued by OHRP.

(e) Prior to starting any research involving human subjects, the contractor shall submit appropriate documentation to the Contracting Officer for institutional review and approval. This documentation may include:

(1) Copies of the human subjects research protocol, all questionnaires, surveys, advertisements, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the human subjects research protocol, questionnaires, surveys, advertisements, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate intervals as designated by the IRB, but not less than annually; and/or

(4) Documentation to support an exemption for the project from the Common Rule [Note: this option is not available for activities that fall under 45 CFR Part 46 Subpart C].

(f) In addition, if the contractor modifies a human subjects research protocol, questionnaire, survey, advertisement, or informed consent form approved by the cognizant IRB, the contractor shall submit a copy of all modified material along with documentation of approval for said modification by the cognizant IRB to the Contracting Officer for institutional review and approval. The contractor shall not implement any IRB approved-modification without written approval by the Contracting Officer.

(g) No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged to the project, until the Contracting Officer approves the required appropriate documentation in writing.

(End of provision)

1352.235-71 Protection of human subjects—exemption. (APR 2010)

(a) Contractor has satisfied the requirements set forth in solicitation #____, related to the Protection of Human Subjects in research. The Government has determined that the research involving human subjects to be conducted under this contract is exempt from the requirements of the Common Rule for the Protection of Human Subjects. The exemption memorandum executed by the Government and the attachments are hereby incorporated by reference into this contract. If contractor uses an informed consent form for the exempt research, contractor must use the informed consent form contained in the attachments in its conduct of research involving human subjects under this contract.

(b) If the conditions upon which the exemption is based should change in any way, contractor shall immediately notify the Contracting Officer in writing of the specified change. The Government will review the change and make a determination as to whether the change requires a change to the exemption approval. Contractor shall not proceed until notified in writing of the Contracting Officer's approval. Contractor shall obtain prior written approval from the Contracting Officer for any change to the existing human subjects protocol or informed consent form before proceeding.

(c) No other research involving human subjects is permitted under this award unless expressly authorized in writing by the Contracting Officer. Such writing will specify the details of the approved research involving human subjects and will be incorporated by reference into this contract.

(d) The Federal Policy for the Protection of Human Subjects (the "Common Rule"), adopted by the Department of Commerce at 15 CFR Part 27, requires contractors to maintain appropriate policies and procedures for the protection of human subjects in research. The Common Rule defines a "human subject" as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The term "research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

(e) The Common Rule also sets forth categories of research that may be considered exempt from this policy. These categories may be found at 15 CFR 27.101(b).

(f) In the event the human subjects research involves pregnant women, prisoners, or children, contractor is also required to follow the guidelines set forth at 45 CFR Part 46 Subpart B, C and D, as appropriate, for the protection of members of a protected class.

(g) Should additional research involving human subjects be required under the contract, prior to beginning such research, contractor shall submit the following documentation to the Contracting Officer:

(1) Documentation to verify that contractor has established a relationship with an appropriate Institutional Review Board ("cognizant IRB"). An appropriate IRB is one that is located within the United States and within the community in which the human subjects research will be conducted;

(2) Documentation to verify that the cognizant IRB is registered with the United States Department of Health and Human Services' Office for Human Research Protections ("OHRP") and is designated as contractor's cognizant IRB;

(3) Documentation to verify that contractor has a valid Federal-wide Assurance (FWA) issued by OHRP; or

(4) Documentation necessary to support a determination that the research is exempt from the requirements of the Common Rule for the Protection of Human Subjects.

(h) Prior to starting any additional research involving human subjects, the contractor shall submit appropriate documentation to the Contracting Officer for institutional review and approval or exemption determination. This documentation may include:

(1) Copies of the human subjects research protocol, all questionnaires, surveys, advertisements, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the human subjects research protocol, questionnaires, surveys, advertisements, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate intervals as designated by the IRB, but not less than annually; and/or

(4) Documentation to support an exemption for the project from the Common Rule [Note: this option is not available for activities that fall under 45 CFR Part 46 Subpart C].

(i) In addition, if the contractor modifies a human subjects research protocol, questionnaire, survey, advertisement, or informed consent form approved by the cognizant IRB, the contractor shall submit a copy of all modified material

along with documentation of approval for said modification by the cognizant IRB to the Contracting Officer for institutional review and approval. The contractor may not implement any IRB approved modification without written approval by the Contracting Officer. No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged to the project, until the Contracting Officer approves the required appropriate documentation in writing.

(End of clause)

1352.235-72 Protection of human subjects—institutional approval. (APR 2010)

(a) This contract/order includes non-exempt human subjects research that must be conducted pursuant to the requirements of the Federal Policy for the Protection of Human Subjects (the "Common Rule"), adopted by the Department of Commerce at 15 CFR Part 27. Contractor has submitted documentation establishing review and approval of the human subjects research protocol, including all informed consent forms, advertisements, and other recruitment materials, by a qualified Institutional Review Board (IRB) that has a current Federal-wide Assurance (FWA) issued by the Department of Health and Human Services (DHHS).

(b) By accepting this contract/order, the contractor certifies the accuracy of the documentation provided to its cognizant IRB and to the Government in support of the human subjects research specified therein. Based upon the contractor's documentation, and following the Government institutional review thereof, the following specific involvement of human subjects in research is hereby approved by the Contracting Officer:

Name of IRB:_____

(IRB # ____)

Title of IRB Protocol:_____

Recruiting Letter Approval Date (if appropriate):_____

Consent Form Approval Date:_____

Assurance of Compliance Number:_____

(c) Unless incorporated by written contract modification approved by the Contracting Officer, no other involvement of human subjects in research under this contract may be undertaken or conducted, or costs incurred and/or charged to the project, except as specified in the study plan reviewed and approved by the cognizant IRB and Government. Therefore, if the contractor modifies a human subjects research protocol, advertisement, or informed consent form approved by the cognizant IRB, contractor shall submit a copy of all modified material, along with documentation of approval for said modification by the cognizant IRB, to the Contracting Officer for agency institutional review and approval. Contractor may not implement any IRB-approved modification without written approval by the Contracting Officer.

Documentation of continuing IRB approval is required each year by the renewal date assigned by the cognizant IRB. Documentation of continuing IRB approval must be submitted to the Government for review and approval as soon as it occurs. Continuing approval of the human subjects research must be obtained from the cognizant IRB and provided to the Government until the research is completed or terminated. The contractor may proceed with previously approved human subjects research, if any, under this contract while the Government is conducting continuing review and approval of the human subjects research protocol. In the event that the Government determines, during the course of its review, that the human subjects research in this contract is not in compliance with the regulations set forth at 15 CFR Part 27, or this contract, the Contracting Officer may take the appropriate enforcement action, including disallowing costs, suspending or terminating the human subjects protocol or the contract, by notifying the contractor in writing.

(d) It is incumbent upon contractor to ensure that continuing IRB review approval occurs in accordance with 15 CFR Part 27. In the event that continuing review approval does not occur as set forth by 15 CFR Part 27, contractor is to notify the Contracting Officer immediately.

(e) Contractor must report all adverse events to the cognizant IRB and to the Contracting Officer. In the event that adverse events are reported to the cognizant IRB and the Contracting Officer, the Government may suspend this contract pending a full review of the adverse event by the cognizant IRB.

(f) If the conditions upon which IRB approval is based should change in any way, contractor shall immediately notify the Contracting Officer, in writing, of the specified change.

(g) Failure to comply with this contract clause will be considered material noncompliance with the contract, and the Contracting Officer may take appropriate enforcement action, including disallowing costs, suspension or termination of the contract.

(End of clause)

1352.235-73 Research involving human subjects—after initial contract award. (APR 2010)

(a) No research involving human subjects is currently included in this contract/task order, and no research involving human subjects is permitted under this contract/task order unless expressly authorized, in writing, by the Contracting Officer.

(b) The Federal Policy for the Protection of Human Subjects (the "Common Rule"), adopted by the Department of Commerce at 15 CFR Part 27, requires that contractors maintain appropriate policies and procedures for the protection of human subjects in research. The Common Rule defines a "human subject" as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The term "research" means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

(c) The Common Rule also sets forth categories of research that may be considered exempt from this policy. These categories are specified at 15 CFR 27.101(b).

(d) In the event that human subjects research involves pregnant women, prisoners, or children, the contractor is also required to follow the guidelines set forth at 45 CFR Part 46 Subparts B, C and D, as appropriate, for the protection of members of a protected class.

(e) Should research involving human subjects become necessary for carrying out this contract/task order, prior to undertaking or conducting such human subjects research, contractor shall submit the following documentation to the Contracting Officer:

(1) Documentation to verify that contractor has established a relationship with an appropriate Institutional Review Board ("cognizant IRB"). An appropriate IRB is one that is located within the United States and within the community in which the human subjects research will be conducted;

(2) Documentation to verify that the cognizant IRB is registered with the United States Department of Health and Human Services' Office for Human Research Protections ("OHRP");

(3) Documentation to verify that contractor has a valid Federal-wide Assurance (FWA) issued by the OHRP.

(f) Prior to starting any research involving human subjects, contractor shall submit appropriate documentation to the Contracting Officer for Government institutional review and approval. This documentation may include:

(1) Copies of the human subjects research protocol, advertisements, recruitment material, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the human subjects research protocol, advertisements, recruitment material, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate intervals as designated by the IRB, but not less than annually; and/or

(4) Documentation to support an exemption for the project from the Common Rule [Note: this option is not available for activities that fall under 45 CFR Part 46 Subpart C].

(g) In addition, if contractor modifies a human subjects research protocol, advertisement, recruitment material, or informed consent form approved by the cognizant IRB, contractor shall submit a copy of all modified material, along with documentation of approval for said modification by the cognizant IRB, to the Contracting Officer for Agency institutional review and approval. Contractor may not implement any IRB-approved modification without written approval by the Contracting Officer.

(h) No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged to the project, until the Contracting Officer approves the required appropriate documentation in writing.

(End of clause)